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| 09/518,408 | 03/03/2000 | Kristin M. Lundy | PC10487A | 7372 |

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| EXAMINER |
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JONES, DWAYNE C

| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 07/08/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/518,408 | LUNDY, KRISTIN M. |
| Examiner | Art Unit | |
| Dwayne C Jones | 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 June 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-9, 11, 12 and 17-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-9, 11, 12 and 17-21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1-9, 11, 12 and 17-21 are pending.
2. Claims 1-9, 11, 12 and 17-21 are rejected.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient descriptive support for the phrase treating an age-related behavioral disorder. In addition, the instant specification does not describe what is meant by the phrase treating an age-related behavioral disorder other than treating cognitive dysfunction syndrome. Structural identifying characteristics of the phrase treating an age-related behavioral disorder are not disclosed except for those treating cognitive dysfunction syndrome. There is no evidence that there is any per se structure/function relationship between the phrase treating an age-related behavioral disorder other than those disclosed, namely treating cognitive dysfunction syndrome. The instant specification does provide an adequate

written description for the phrase of treating an age-related behavioral disorder.

Accordingly, these claims fail to comply with the written description requirement.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of these claims makes reference to the compound of Formula I; however, these claims fail to provide the artisan with a structure to coincide with the compound of Formula I. It is suggested that either the compound and the embodiments of Formula I be incorporated into an independent claim or each of these claims could be made to depend on independent claim 1 and accordingly make reference to the compound of Formula 1 as defined in claim 1 or something equivalent in meaning and scope.

7. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 states the phrase, "sufficient to improve cognitive processing." However, this claim is directed to treating memory loss. It is unclear as to why this phrase is needed in this claim. It is noted that claim 3 is directed to a method of improving the cognitive processing of a companion animal.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-9, 11, 12 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Malley et al. of U.S. Patent No. 5,494,908 is maintained and repeated for both the above-stated and reasons of record. O'Malley et al. teach of the benzisoxazole compounds and that these compounds are anticholinesterase inhibitors. O'Malley et al. also teach that these compounds are effective in the treatment of Alzheimer's disease, (see abstract and columns 19-26). O'Malley et al. also teach of pharmaceutical preparations of these compounds, (see column 25). The compounds of O'Malley et al. possess an identical benzisoxazolyl and piperidinyl moieties and other identical substituents. In addition, the physiological activities between the compounds of O'Malley et al. and the instant invention are analogous; in fact both are anticholinesterase inhibitors. The claims differ from the prior art by having a linking

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group other than an alkyl group that is interrupted by an amino group, which corresponds to applicant's variable of Y. One having ordinary skill in the art would have been motivated to select the claimed compound with the expectation that substitution of a hydrocarbyl or an oxy hydrocarbyl moiety for an amino hydrocarbyl in the very same position as that of the instantly claimed variable Y would not significantly alter the analogous properties of the compound of the O'Malley et al. reference due to its close structural similarity of the compounds. Moreover, although the prior art reference of O'Malley et al. do not specifically teach of treating of the cognitive disorders recited by the instant claims, O'Malley et al. do state the benzisoxazole compounds and their salts are effective in the treatment of various memory dysfunctions characterized by a decreased cholinergic function such as Alzheimer's disease, (see column 2, lines 19-25). Clearly, it would have been obvious to one having ordinary skill in the art to employ these benzisoxazole compounds for disorders related to memory dysfunctions where there is a decrease in the cholinergic function, as taught by O'Malley et al, especially since the compounds disclosed by O'Malley et al. are structural analogous as well as possessing similar and analogous properties.

Obviousness-type Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. The rejection of claims 1-9, 11, 12 and 17-21 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S.

Patent No. 5,538,984 is maintained and repeated for the outstanding reasons of record.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and U.S. Patent No. 5,538,984 are directed to the improving of a cognitive disorder for the improvement in memory or even treating dementia and Alzheimer's disease with the administration of the compounds of formula (I). In addition, the prior art reference of Villalobos et al. is directed to compounds and pharmaceuticals that, "are useful in enhancing memory in patients suffering from dementia and Alzheimer's disease", (see column 1, lines 13-18). First, the prior art reference of Villalobos et al. is specifically relevant to treating "mammals" which most certainly provides motivation to embrace companion mammals such as dogs and cats. In addition, it is well established in the art that both dementia as well as Alzheimer's disease are commonly associated with disorders afflicting older mammals. Accordingly, it would have been obvious to one having ordinary skill in the art to use the teachings of Villalobos et al. for treating age-related disorders, such as dementia, in a mammal, which would obviously include companion mammals.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.

Dwayne C. Jones
DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
July 7, 2003